IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF TENNESSEE

UNITED STATES OF AMERICA, Plaintiff, v. KEYSTONE LABORATORIES, INC., a corporation, MELINDA MENKE and ELIZABETH JUMET, individuals, Defendants.	)	Civil Action No. 18-2656 CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by and through its undersigned attorneys, having filed a Complaint for Permanent Injunction against Keystone Laboratories, Inc., a corporation, and Melinda Menke and Elizabeth Jumet, individuals (hereinafter, collectively, "Defendants"), and Defendants having appeared and consented to entry of this Decree without contest, and before any testimony has been taken, and the United States of America, having consented to this Decree;

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of this action and all parties to this action. Venue is proper in this District under 28 U.S.C. § 1391(b) and (c).

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce articles of drug, as defined by 21 U.S.C. § 321(g)(1), that are adulterated

within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice ("CGMP") for drugs, see e.g., 21 C.F.R. Parts 210 and 211 (hereinafter, "drug CGMP requirements").

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or delivering for introduction, or causing to be introduced or delivered for introduction, into interstate commerce drugs that are misbranded within the meaning of 21 U.S.C. § 352(c), (f)(1), and (o).

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing drugs that they hold for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing drugs that they hold for sale after shipment of one or more of their components in interstate commerce to become misbranded within the meaning of 21 U.S.C. § 352(c), (f)(1), and (o).

7. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise (the "Associated Person(s)") are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly manufacturing, processing, packing, labeling, holding, and/or distributing any drug from Defendants' facility at 1103 Kansas Street, Memphis, Tennessee, or at or from any facility owned or operated by Defendants ("Defendants' Facilities"), unless and until:

A. Defendants' methods, facilities, and controls used to manufacture, process, pack, label, hold, and distribute drugs are established, operated, and administered in conformity with drug CGMP requirements, see, e.g., 21 C.F.R. Parts 210 and 211;

B. Defendants list each of their drugs with FDA, in accordance with 21 U.S.C. § 360(j); 21 C.F.R. §§ 207.41 and 207.49;

C. Defendants establish and document management control over Quality Assurance ("QA") and Quality Control ("QC") for Defendants' Facilities to ensure continuous compliance with the Act, its implementing regulations, and this Decree. Responsibility for management control over QA and QC shall be vested in an individual who shall be authorized and responsible for all QA and QC functions at all of Defendants' Facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive written QA and QC program ("QA/QC program") as described in paragraph 7.F.iii, to ensure that all drugs manufactured, processed, packed, labeled, held, and/or distributed directly or indirectly by Defendants have the safety, identity, strength, quality, and purity that they purport or are represented to possess, and are in compliance with the provisions of this Decree;

D. Defendants retain, at their expense, an independent person or persons (the "CGMP Expert") to conduct inspections of Defendants' operations; to review Defendants' procedures and methods for manufacturing, processing, packing, labeling, holding, and distributing drugs; and to determine whether Defendants' methods, facilities, and controls are operated and administered in conformity with this Decree, the Act, and its implementing regulations. The CGMP Expert shall be qualified by education, training, and experience to conduct such inspections; have specific expertise in evaluating compliance with drug CGMP requirements; have expertise in microbiology; and be without personal or financial ties (other

than a consulting agreement between the parties) to Defendants' officers or employees or their families. Defendants shall notify FDA in writing of the identity and qualifications of the CGMP Expert within ten (10) business days of retaining such CGMP Expert;

E. Before the CGMP Expert begins the inspection described in Paragraph 7.F., Defendants shall work with the CGMP Expert to develop and collectively submit to FDA a work plan that includes, but is not limited to: (i) a protocol for the CGMP Expert to inspect Defendants' Facilities, and (ii) the methodology that the CGMP Expert will use to ensure that Defendants' corrective actions are implemented, and that Defendants' laboratory testing practices and manufacturing, processing, packing, labeling, holding, and distribution of drugs are designed, operated, and will be continuously administered in conformity with drug CGMP requirements;

F. The CGMP Expert shall perform a comprehensive inspection of Defendants' Facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs. The CGMP Expert shall determine whether Defendants' Facilities and the methods and controls used to manufacture, process, package, label, hold, and distribute drugs are in compliance with the Act, its implementing regulations, and this Decree. The CGMP Expert's report of the inspection shall be submitted to FDA and shall include, but not be limited to, the following:

i. A certification that she or he has inspected Defendants' Facilities, processes, methods, and controls;

ii. An evaluation of Defendants' current state of compliance with respect to the deviations set forth on all Forms FDA-483 issued to Defendants prior to and including November 16, 2017;

iii. An evaluation of whether Defendants have established and implemented a comprehensive quality system with reliable manufacturing operations and a comprehensive written QA/QC program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The QA/QC program shall ensure that all drugs manufactured, processed, packed, held, and distributed at or from Defendants' Facilities have the safety, identity, strength, quality, and purity that they purport or are represented to possess, and are in compliance with the provisions of this Decree. In addition, the QA/QC program and manufacturing operations shall include resources, systems, procedures, and appropriate individuals with necessary authority to ensure that:

(a) Defendants follow written production and process control procedures in executing production and process control functions and to record and justify any deviation from the procedures;

(b) Defendants' manufacturing operations are conducted using suitably designed equipment, facilities, and processes with demonstrated capability to assure reliable manufacturing performance and consistent drug quality;

(c) Defendants, in a timely manner, (1) thoroughly investigate product deviations, reports of complaints regarding Defendants' products, and any unexplained discrepancy or the failure of a batch of drug or any of its components to meet any product or component specifications; (2) extend such investigations to other batches of the same drug and other drugs that may have been associated with the specific failure or discrepancy; and (3) take required corrective actions for all products and components that fail to meet their specifications;

(d) Defendants establish systems to ensure that their written standard operating procedures ("SOPs") addressing all facets of drug CGMP requirements are controlled

and periodically re-evaluated by the QA/QC unit so that they remain in continuous compliance. Such established systems must require that: (1) Defendants' QA personnel are promptly notified in writing of all deviations or problems that could affect the safety, identity, strength, quality, and purity of any drug; (2) Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations or problems; and (3) there are systems to ensure that written SOPs are continuously followed, including written SOPs that specify the responsibilities and procedures applicable to QA and QC personnel;

iv. A determination of whether Defendants have established and implemented adequate procedures, processes, equipment, and facilities designed to prevent microbiological contamination of each component and batch of drug required to be free of objectionable microorganisms;

v. A determination of whether Defendants have qualified their water system and developed and implemented appropriate specifications and test plans to ensure that such water is of the quality needed to manufacture their drugs;

vi. A determination of whether the test methods used to determine the stability of Defendants' drug products have been established, validated, and documented, including but not limited to conducting validation to ensure that such methods are stability-indicating, i.e, they can detect the changes with time of the chemical, physical, or microbiological properties of Defendants' drug products, and that such methods are specific so that the contents of active ingredients, degradation products, impurities, and other components of interest can be accurately measured without interference;

vii. A determination of whether Defendants have established and are following written procedures for equipment cleaning and maintenance, including utensils, used in the manufacture, processing, preparing, packing, or holding of drugs;

viii. A determination of whether Defendants have established and are following laboratory controls that include scientifically sound and appropriate specifications, standards, sampling plans, and test procedures designed to assure that drug components, drug product containers, closures, in-process materials, and labeling, and drug products conform to appropriate standards of identity, strength, quality, and purity;

ix. An evaluation of whether Defendants' QA/QC unit reviews and approves all drug production and control records to determine compliance with all established written procedures and specifications before a batch is released or distributed; and

x. A determination of whether Defendants have corrected all violations set forth in Forms FDA-483 from all FDA inspections prior to and including November 16, 2017;

G. Defendants report to FDA in writing the actions that they have taken to: (i) correct all violations brought to Defendants' attention by the CGMP Expert and all violations set forth in FDA's Forms FDA-483 from all FDA inspections prior to and including November 16, 2017; and (ii) ensure that the methods used in, and the facilities and controls used for manufacturing, processing, packing, labeling, holding, and distributing drugs are designed, operated and administered and will be continuously operated and administered in conformity with this Decree, the Act, and its implementing regulations. Defendants shall include with their report a copy of a written certification from the CGMP Expert that Defendants are in compliance with this Decree, the Act, and its implementing regulations;

H. FDA, as and when it deems necessary, inspects Defendants' operations to determine whether the requirements of this Decree have been met, and whether Defendants' operations are otherwise operated in conformity with the Act and its implementing regulations;

I. Defendants pay all costs and expenses incurred under paragraph 7 for FDA inspections, investigations, supervision, reviews, examinations, evaluations, and analyses, at the rates set forth in paragraph 17 of this Decree; and

J. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraph 7.A through G and I. In no circumstance shall FDA's silence be construed as a substitute for written notification.

8. Upon entry of this Decree, Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons or entities in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, franchisees, affiliates, and "doing business as" entities), who have received actual notice of this Decree by personal service or otherwise (the "Associated Person(s)") are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly packing, labeling, holding, and/or distributing any drug manufactured for Defendants by a third party ("Defendants' Contract Manufacturer"), unless and until:

A. Defendants establish and document management control over QA and QC for Defendants' Facilities to ensure continuous compliance with the Act, its implementing regulations, and this Decree. Responsibility for management control over QA and QC shall be vested in an individual who shall be authorized and responsible for all QA and QC functions at Defendants' Facilities, including ensuring the establishment, implementation, and maintenance of a comprehensive written QA and QC program ("QA/QC program"), to ensure that all of

Defendants' drugs, whether manufactured, processed, packed, labeled, held, and/or distributed directly or indirectly by Defendants and/or Defendants' Contract Manufacturer, have the safety, identity, strength, quality, and purity that they purport or are represented to possess, and are in compliance with the provisions of this Decree. The QA/QC program and manufacturing operations shall include resources, systems, procedures, and appropriate individuals with necessary authority to ensure that:

i. Defendants follow written production and process control procedures in executing production and process control functions and to record and justify any deviation from the procedures;

ii. Defendants' Contract Manufacturer's manufacturing operations are conducted using suitably designed equipment, facilities, and processes with demonstrated capability to assure reliable manufacturing performance and consistent drug quality;

iii. Defendants, in a timely manner, (1) thoroughly investigate product deviations, reports of complaints regarding Defendants' products, and any unexplained discrepancy or the failure of a batch of drug or any of its components to meet any product or component specifications; (2) extend such investigations to other batches of the same drug and other drugs that may have been associated with the specific failure or discrepancy; and (3) take required corrective actions for all products and components that fail to meet their specifications;

iv. Defendants establish systems to ensure that their written SOPs addressing all facets of drug CGMP requirements are controlled and periodically re-evaluated by the QA/QC unit so that they remain in continuous compliance. Such established systems must require that: (1) Defendants' QA personnel are promptly notified in writing of all deviations or problems that could affect the safety, identity, strength, quality, and purity of any of Defendants'

drugs; (2) Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations or problems; and (3) there are systems to ensure that written SOPs are continuously followed, including written SOPs that specify the responsibilities and procedures applicable to QA and QC personnel; and

v. Defendants ensure that, prior to distribution, their QC unit approves or rejects all of Defendants' drugs that are manufactured, processed, packed, or held under contract by Defendants' Contract Manufacturer.

B. Defendants retain, at their expense, an independent person or persons (the "Expert") to conduct inspections of Defendants' operations; to review Defendants' procedures and methods for packing, labeling, holding, and distributing drugs; and to determine whether Defendants' methods, facilities, and controls are operated and administered in conformity with this Decree, the Act, and its implementing regulations. The Expert shall be qualified by education, training, and experience to conduct such inspections; have specific expertise in evaluating compliance with the Act and its implementing regulations; have expertise in microbiology; and be without personal or financial ties (other than a consulting agreement between the parties) to Defendants' officers or employees or their families. Defendants shall notify FDA in writing of the identity and qualifications of the Expert within ten (10) business days of retaining such Expert;

C. Before the Expert begins the inspection described in Paragraph 8.B., Defendants shall work with the Expert to develop and collectively submit to FDA a work plan that includes, but is not limited to: (i) a protocol for the Expert to inspect Defendants' Facilities, and (ii) the methodology that the Expert will use to ensure that Defendants' corrective actions are

implemented, and that Defendants' packing, labeling, holding, and distribution of drugs are designed, operated, and will be continuously administered in conformity with the Act and its implementing regulations;

D. The Expert shall perform a comprehensive inspection of Defendants' Facilities and the methods and controls used to package, label, hold, and distribute drugs. The Expert shall determine whether Defendants' Facilities and the methods and controls used to package, label, hold, and distribute drugs are in compliance with the Act, its implementing regulations, and this Decree. The Expert's report of the inspection shall be submitted to FDA and shall include, but not be limited to, the following:

i. A certification that she or he has inspected Defendants' Facilities, processes, methods, and controls;

ii. An evaluation of whether Defendants have established and implemented a comprehensive quality system with reliable manufacturing operations and a comprehensive written QA/QC program that is adequate to ensure continuous compliance with the Act, its implementing regulations, and this Decree. The QA/QC program shall ensure that all drugs manufactured, processed, packed, labeled, held, and distributed at or from Defendants' Facilities or Defendants' Contract Manufacturer, have the safety, identity, strength, quality, and purity that they purport or are represented to possess, and are in compliance with the provisions of this Decree. In addition, the QA/QC program shall include resources, systems, procedures, and appropriate individuals with necessary authority to ensure that:

(a) Defendants follow written production and process control procedures in executing production and process control functions and to record and justify any deviation from the procedures;

(b) Defendants, in a timely manner, (1) thoroughly investigate product deviations, reports of complaints regarding Defendants' products, and any unexplained discrepancy or the failure of a batch of drug or any of its components to meet any product or component specifications; (2) extend such investigations to other batches of the same drug and other drugs that may have been associated with the specific failure or discrepancy; and (3) take required corrective actions for all products and components that fail to meet their specifications; and

(c) Defendants establish systems to ensure that their written SOPs addressing all facets of drug CGMP requirements are controlled and periodically re-evaluated by the QA/QC unit so that they remain in continuous compliance. Such established systems must require that: (1) Defendants' QA personnel are promptly notified in writing of all deviations or problems that could affect the safety, identity, strength, quality, and purity of any of Defendants' drugs; (2) Defendants' QA personnel participate in or monitor the implementation and verification of corrective actions to prevent future occurrences of such deviations or problems; and (3) there are systems to ensure that written SOPs are continuously followed, including written SOPs that specify the responsibilities and procedures applicable to QA and QC personnel;

iii. An evaluation of whether Defendants' QA/QC unit reviews and approves all drug production and control records to determine compliance with all established written procedures and specifications before a batch is released or distributed; and

iv. A determination of whether Defendants have processes in place to ensure that when one or more drug manufacturing, processing, packing, labeling, holding, selling, and distributing functions are contracted or outsourced to Defendants' Contract Manufacturer,

responsibilities are defined for each party involved, periodic audits of the contracted or outsourced facility are performned by Defendants, the contracted or outsourced site is appropriately monitored by Defendants, and appropriate product and process information is promptly transferred from the Defendants to Defendants' Contract Manufacturer;

E. FDA, as and when it deems necessary, inspects Defendants' operations to determine whether the requirements of this Decree have been met, and whether Defendants' operations are otherwise operated in conformity with the Act and its implementing regulations;

F. Defendants pay all costs and expenses incurred under paragraph 8 for FDA inspections, investigations, supervision, reviews, examinations, evaluations, and analyses, at the rates set forth in paragraph 17 of this Decree; and

G. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements set forth in paragraph 8.A through D. and F. In no circumstance shall FDA's silence be construed as a substitute for written notification.

9. Before Defendants may commence manufacturing or distributing any drug or resume or continue the manufacture or distribution of any previously distributed drug, whether distributed by Defendants or Defendants' Contract Manufacturer, Defendants shall first notify FDA of their intention to do so, and shall not distribute or cause to be distributed such drug unless and until:

A. Defendants retain, at their expense, an independent person or person(s) (the "Labeling and Monograph Expert"), who is without any personal or financial ties (other than the retention agreement) to Defendants and their families, and who, by reason of background, training, education, or experience, is qualified to review the formulation and labeling of Defendants' drug products to determine whether such products conform to the requirements set forth at 21 C.F.R. Part 201, Subpart C and in any applicable final or pending final over-the-

counter ("OTC") drug monograph and whether the labels and labeling for such products comply with the Act and its implementing regulations, including, but not limited to, 21 U.S.C. § 352(c), (f)(1), and (o). Defendants shall notify FDA in writing of the identity and qualifications of the Labeling and Monograph Expert as soon as they retain such expert. The Labeling and Monograph Expert may be the same person as the CGMP Expert described in paragraph 7.D or Expert described in paragraph 8.B.;

B. For each drug product that Defendants propose to directly or indirectly manufacture, process, pack, label, hold, or distribute (including but not limited to medicated Better Braids Spray, medicated Better Braids Un-braid, medicated Better Braids Shampoo, medicated Better Braids Leave-In-Conditioner, Ultra Glow Fade Cream with Complexion Bar, Ultra Glow Fade Cream Oily Skin, Ultra Glow Fade Cream Normal Skin, and Ultra Glow Skin Tone Cream), the Labeling and Monograph Expert performs a comprehensive review of the product's formulation and its proposed labeling, including but not limited to product labels, promotional materials, websites, social media pages, or other media owned, operated, or controlled by any of the Defendants or over which any of the Defendants has editorial control, to determine whether the product: (i) is subject to an FDA approved new drug application or abbreviated new drug application filed pursuant to 21 U.S.C. §355 or conforms to an applicable final or pending final OTC drug monograph; (ii) conforms to all labeling requirements under the Act and its implementing regulations; and (iii) is not otherwise misbranded;

C. For each drug product the Labeling and Monograph Expert reviews pursuant to paragraph 9.B, the Defendants ensure that the Labeling and Monograph Expert certifies in writing to FDA that:

i. the Labeling and Monograph Expert has reviewed the drug product, its formulation, and labeling;

ii. the drug product's formulation and labeling conform to any and all applicable final or pending final OTC drug monographs and to all applicable labeling requirements under the Act and its implementing regulations. If a pending final OTC monograph subsequently becomes final and effective, it may be necessary to reformulate and/or relabel such a product to conform to its requirements, or, in the alternative, to seek FDA approval of a new drug or abbreviated new drug application under 21 U.S.C. § 355; and

iii. the drug is not otherwise misbranded.

As part of this certification, the Labeling and Monograph Expert shall attach the labeling reviewed together with a detailed and complete report of the results of the Labeling and Monograph Expert's labeling review, including references to the applicable final or pending final OTC drug monograph and labeling regulations consulted by the expert in conducting the review;

D. Defendants have provided FDA with any additional information requested by the agency to review the Labeling and Monograph Expert's certification, including any records held by Defendants' Contract Manufacturer; and

E. FDA notifies Defendants in writing that Defendants appear to be in compliance with the requirements in paragraph 9.A through D, the Act, and its implementing regulations. In no circumstance may FDA's silence be construed as substitute for written notification.

10. Upon entry of this Decree, Defendants and each and all of their Associated Person(s) who receive notice of this Decree by personal service or otherwise are permanently restrained and enjoined, pursuant to 21 U.S.C. § 332(a), from directly or indirectly doing or causing to be done any act that:

A. Violates the Act, 21 U.S.C. § 331(a), by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352;

B. Violates the Act, 21 U.S.C. § 331(k), by causing any drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B) or misbranded within the meaning of 21 U.S.C. § 352, while it is held for sale after shipment of one or more of its components in interstate commerce; and

C. Failing to implement and continuously maintain the requirements of the Act, its implementing regulations, and this Decree.

11. Within fifteen (15) business days after entry of this Decree, Defendants shall give written notice to FDA that, at their own expense and under FDA's supervision, they are prepared to destroy: (i) all drugs in their possession, custody, or control that are subject of recalls; (ii) all drugs that customers have returned to Defendants in response to a recall or recalls; (iii) all other drugs in their possession, custody, or control, including all in-process and finished drugs and drug components. Defendants' notice shall specify the proposed time, place, and method of destruction (hereafter, "destruction plan"). With respect to any recalled drugs that come into Defendants' possession, custody, or control after destruction has commenced under this paragraph, Defendants shall quarantine any such products, notify FDA in writing of their receipt, and destroy any such products under FDA's supervision no later than fifteen (15) calendar days after their receipt. Defendants shall not commence or permit any other person to commence destruction until they have received FDA's written approval of the destruction plan and written authorization from FDA to commence the destruction. Defendants shall not cause any drugs to

be disposed of in a manner contrary to the Act, or other laws of the United States, or of any State or Territory (as defined in the Act) in which they are disposed. Within fifteen (15) business days after receiving authorization from FDA to commence destroying the drugs, Defendants shall, under FDA supervision, complete the destruction in compliance with this Decree. Defendants shall reimburse FDA, at the rates set forth in paragraph 17, for the supervision of the destruction within ten (10) business days after receiving notice of such costs from FDA.

12. After Defendants have complied with paragraphs 7.A through G and I, 8.A through D and F, and 9.A through D, and FDA has notified Defendants in writing pursuant to paragraphs 7.J, 8.G, and 9.E, Defendants shall retain an independent person or persons (the "Auditor") at Defendants' expense to conduct audit inspections of Defendants' operations, not less than once every six (6) months for a period of no less than five (5) years. The Auditor shall be qualified by education, training, and experience to conduct such inspections, and shall be without personal or financial ties (other than a consulting agreement entered into by the parties) to Defendants' officers or employees or their families. The Auditor may be the same person or persons described as the CGMP Expert in paragraph 7.D, or Expert described in paragraph 8.B.

A. At the conclusion of each audit inspection, the Auditor shall prepare a written audit report (the "Audit Report") analyzing whether Defendants' are in compliance with this Decree, the Act, and its implementing regulations, and identifying in detail any deviations from the foregoing ("Audit Report Observations"). As part of every Audit Report, except the first, the Auditor shall assess the adequacy of corrective actions taken by Defendants to correct all previous Audit Report Observations. The Audit Reports shall be delivered contemporaneously to Defendants and FDA by courier service or overnight delivery service, no later than twenty (20) business days after the date the audit inspections are completed. If any Audit Report

identifies any deviations from the Act, its implementing regulations, or this Decree, FDA may, in its discretion, require that the five (5) year auditing cycle be extended or begin anew. In addition, Defendants shall maintain complete Audit Reports and all of their underlying data in separate files at Defendants' Facilities and shall promptly make the Audit Reports and underlying data available to FDA upon request.

B. If an Audit Report contains any adverse Audit Report Observations, Defendants shall, within thirty (30) business days of receipt of the Audit Report, correct those observations, unless FDA notifies Defendants that a shorter time period is necessary. If, after receiving the Audit Report, Defendants believe that correction of any adverse Audit Report Observation will take longer than thirty (30) business days, Defendants shall, within ten (10) business days of receipt of the Audit Report, propose a schedule for completing corrections ("Correction Schedule") and provide justification for the additional time. Defendants shall complete their corrections within thirty (30) business days, unless FDA approves in writing the Correction Schedule, in which case Defendants shall complete all corrections according to the approved Correction Schedule. In no circumstance shall FDA's silence be construed as a substitute for written approval. Within thirty (30) business days of Defendants' receipt of an Audit Report, or within the time period provided in a Correction Schedule approved by FDA, the Auditor shall review the actions taken by Defendants to correct the adverse Audit Report Observation(s). Within five (5) business days of the beginning of that review, the Auditor shall report in writing to FDA whether each of the adverse Audit Report Observations has been corrected and, if not, which adverse Audit Report Observations remain uncorrected.

13. Upon entry of this Decree, if at any time FDA determines, based on the

results of an inspection (including but not limited to an inspection of Defendants' Contract Manufacturer), the analysis of a sample, a report, a review, or any other information, that Defendants or Defendants' Contract Manufacturer have failed to comply with any provision of this Decree, have violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action, including, but not limited to, ordering Defendants to immediately take one or more of the following actions:

A. Cease manufacturing, processing, packing, labeling, holding, selling, or distributing any or all drugs;

B. Recall, at Defendants' sole expense, any drug that is adulterated, misbranded, or otherwise in violation of this Decree, the Act, or its implementing regulations;

C. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

D. Submit additional notifications, reports, or any other materials or information to FDA;

E. Issue a safety alert;

F. Issue a press release; and

G. Take any other corrective actions as FDA, in its discretion, deems necessary to bring Defendants and/or their products into compliance with this Decree, the Act, and its implementing regulations.

The provisions of this paragraph shall be apart from, and in addition to, all other remedies available to FDA.

14. Upon receipt of any order issued by FDA pursuant to paragraph 13, Defendants shall immediately and fully comply with the terms of the order. Any cessation of operations or other action described in paragraph 13 shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations, and that Defendant may, therefore, resume operations. The cost of FDA inspections, sampling, testing, travel time, and subsistence expenses to implement the remedies set forth in Paragraph 13 shall be borne by Defendants at the rates specified in Paragraph 17.

15. FDA shall be permitted, without prior notice, and as FDA deems necessary, to make inspections of Defendants' Facilities and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and its implementing regulations. During inspections, FDA shall be permitted to have immediate access to buildings, equipment, raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other materials therein; to take photographs and make video recordings; to take samples of raw ingredients, in-process materials, finished products, containers, packing material, labeling, and other promotional materials; and to examine and copy all records relating to the manufacture, processing, packing, labeling, holding, and distribution of any and all of Defendants' products and their components. The inspection shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to conduct inspections under the Act, 21 U.S.C. § 374.

16. Defendants shall promptly provide any information or records to FDA upon request regarding the receiving, manufacturing, preparing, processing, packing, labeling, holding, and distribution of any of their products.

17. Defendants shall reimburse FDA for the costs of all inspections, investigations, supervision, reviews, examinations, evaluations, and analyses that FDA deems necessary to evaluate Defendants' compliance with this Decree at the standard rates prevailing at the time the costs are incurred. As of the date this Decree is signed by the parties, the rates are: $93.26 per hour or fraction thereof per representative for inspection work; $111.77 per hour or fraction thereof per representative for analytical work; and $0.535 per mile for travel expenses for travel by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per representative and per day for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA's supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of this Court.

18. Within ten (10) business days after entry of this Decree, Defendants shall post a copy of this Decree in a common area at Defendants' Facilities and at any other location at which Defendants conduct business, and shall ensure that the Decree remains posted for as long as it remains in effect. Within twenty (20) business days after entry of this Decree, Defendants shall provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph.

19. Within ten (10) business days after entry of this Decree, Defendants shall provide a copy of the Decree by personal service or certified mail (restricted delivery, return receipt requested) to each Associated Person(s). Within twenty (20) business days after entry of this Decree,

Defendants shall provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, and identifying the names, addresses, and positions of all persons who have received a copy of this Decree.

20. In the event that Defendants become associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree, by personal service or certified mail (restricted delivery, return receipt requested), to such Associated Person(s). Each time a Defendant becomes associated with an additional Associated Person(s), it shall, within ten (10) business days of commencement of the association, provide to FDA an affidavit stating the fact and manner of its compliance with this paragraph, and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph. Within ten (10) business days of receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

21. Defendants shall notify FDA in writing at least ten (10) business days before any change in ownership, name, or character of its business that occurs after entry of this Decree, including an incorporation, reorganization, creation of a subsidiary, relocation, dissolution, bankruptcy, assignment, sale, or any other change in the structure or identity of Keystone Laboratories, Inc., or the sale or assignment of any business assets, such as buildings, equipment, or inventory, that may affect obligations arising out of this Decree. Defendants shall provide a copy of this Decree to any potential successor or assignee at least twenty (20) business days prior to any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten (10) business days prior to such assignment or change in ownership.

22. All decisions specified in this Decree shall be vested in the discretion of FDA and shall be final. When contested by Defendants, FDA's decisions under this Decree shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

23. All notifications, correspondence, and communications required to be sent to FDA by the terms of this Decree shall be addressed to Program Division Director, Office of Pharmaceutical Quality Operations Division II, United States Food and Drug Administration, 404 BNA Drive, Building 200, Suite 500, Nashville, TN 37172, and shall reference the case name and civil action number.

24. Should Defendants fail to comply with any provision of this Decree, the Act, or its implementing regulations, it shall pay to the United States of America the sum of ten thousand dollars ($10,000) in liquidated damages for each day such violation continues and an additional sum of five thousand dollars ($5,000) in liquidated damages for each violation of this Decree, the Act, or its implementing regulations, and an additional sum equal to five (5) times the retail value of each shipment (including any shipment Defendants cause to be distributed) of an adulterated or misbranded drug in liquidated damages for each such unlawful shipment. Defendants understand and agree that the liquidated damages specified in this paragraph are not punitive in nature and their imposition does not in any way limit the ability of the United States of America to seek, and the Court to impose, additional criminal or civil penalties based on conduct that may also be the basis for payment of the liquidated damages.

25. Should the United States of America bring, and prevail in, a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United

States of America for its attorneys' fees and overhead, investigational and analytical expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, administrative court costs, and any other costs or fees relating to such proceedings.

26. If Defendants petition the Court for relief from this Decree and, at the time of the petition, in FDA's judgment, Defendants have maintained a state of continuous compliance with this Decree, the Act, and all applicable regulations, for five (5) years after entry of this Decree, Plaintiff will not oppose such petition.

27. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED.

Dated this __ day of _____ 2018.

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UNITED STATES DISTRICT JUDGE

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We hereby consent to the entry of the foregoing Consent Decree:

MELINDA MENKE, individually and on behalf of Keystone Laboratories, Inc.

ELIZABETH JUMET, individually and on behalf of Keystone Laboratories, Inc.

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